INNOVATIVE APPROACHES TO DISEASE PREVENTION THROUGH BEHAVIOR CHANGE

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RFA: OD-98-002

P.T.

Office of Behavioral and Social Sciences Research
Office of Disease Prevention
Office of Research on Women's Health
Office of Alternative Medicine
Office of Dietary Supplements
National Cancer Institute
National Heart, Lung, and Blood Institute
National Institute on Aging
National Institute on Alcohol Abuse and Alcoholism
National Institute of Allergy and Infectious Diseases
National Institute of Arthritis and Musculoskeletal and Skin Disease
National Institute of Child Health and Human Development
National Institute of Dental Research
National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Mental Health
National Institute of Neurological Disorders and Stroke
National Institute of Nursing Research
American Heart Association

Letter of Intent Receipt Date: April 1, 1998
Application Receipt Date: May 21, 1998

PURPOSE

The above named organizations invite applications for a four year research grant program to test interventions designed to achieve long-term health behavior change. The health behaviors of interest-- tobacco use, insufficient exercise, poor diet, and alcohol abuse--are among the top ten causes for morbidity and premature mortality. This Request for Applications (RFA) solicits intervention studies aimed at either comparing alternative theories related to mechanisms

involved in behavior change, or assessing the utility of a particular theoretical model for changing two or more health-related behaviors, rather than simply demonstrating the efficacy of a single behavior change program.

The sponsoring organizations are jointly issuing this Request for Applications (RFA) because tobacco use, exercise, diet, and alcohol abuse are behaviors with implications for a wide array of health outcomes for both women and men, including cancer, infectious and allergic diseases, osteoporosis, diabetes, heart disease, arthritis, depression, periodontal diseases, obesity, and kidney diseases, as well as related outcomes such as mood and affect, functional impairment, disability, quality of life, and health care utilization. The behaviors of interest also share a common conceptual basis for change, and can benefit from findings from research on learning, motivation, risk perception, decision making, social influence, and the like. Because many facets of understanding the process of behavioral change are shared, a combined effort is efficient for the agencies and scientists alike. The RFA is intended to not only address the missions of the different organizations, but also go beyond what any single organization would be likely to accomplish individually.

Throughout the life span, the health effects of social and behavioral factors such as smoking, drinking, physical activity, and diet have been dramatically demonstrated. Most of these studies, however, have examined one health practice at a time (e.g., increased exercise) or focused on an individual intervention approach (individual skill building techniques), despite complex interactions between various health habits and their maintenance through reinforcement at several levels: the individual, family, and community as a whole. Most previous research has targeted easy-to-reach populations, rather than testing the effectiveness and applicability of interventions for vulnerable populations in diverse ethic/minority, groups, age groups, and geographic regions.
Past efforts have typically focused on short term behavioral change, yielding little information on how change, once achieved, can be maintained over the long term. The goal of the present initiative is to address these important gaps in our knowledge regarding effective disease prevention strategies.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000" a PHS-led national activity for setting priority areas. This RFA, "Innovative Approaches to Disease Prevention through Behavior Change," is related to the priority areas of physical activity and fitness, nutrition, tobacco, alcohol and other drugs, mental health and mental disorders, maternal and infant health, heart disease and stroke,

cancer, diabetes and chronic disabling conditions, immunization and infections diseases, and clinical preventive services. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No.017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800).

ELIGIBILITY

Applications may be submitted by any domestic for-profit or non-profit organizations, public or private, such as universities, colleges, hospitals, laboratories, units of State and local governments, or eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

MECHANISM OF SUPPORT

This RFA will use the NIH individual research project grant (R01) mechanism of support. Submission of coordinated R01 applications which permit replication of an intervention in multiple sites is an option. However, the combined budgets for these coordinated applications should stay within the budgetary guidelines for a single project grant.

FUNDS AVAILABLE

It is anticipated that for fiscal year 1999, $3,700,000 total funds (direct and indirect costs) will be available. Award of grants pursuant to this RFA is contingent upon receipt of both sufficiently meritorious applications and funds for this purpose. Between 5 and 8 awards are anticipated, not to exceed $700,000 in annual total cost per individual grant. The exact amount of funding awarded will depend on the quality of applications and the availability of funds.

Applicants should provide a detailed time frame describing what specific activities are to occur throughout the proposed grant period, justifying time estimates. Applicants may request support for up to four years. The usual PHS policies governing grants administration and management will apply. Annual awards will be made, subject to continued availability of funds and progress achieved. This RFA is a one-time solicitation. At the end of each project's official award period, a competitive renewal application may be submitted for peer review and competition for support through the regular grant programs of the NIH. It is anticipated that awards resulting from RFA OD-98-002 may begin as early as April 1, 1999. Administrative adjustments in project period or amount of support may be required at the time of the award. Since a variety of approaches would

represent valid responses to this RFA, it is anticipated that there will be a range of costs among the grants awarded. All current policies and requirements that govern the research grant programs of the NIH will apply to grants awarded in connection with this RFA.

RESEARCH OBJECTIVES

Background

The RFA is responsive to several recent reports calling for increased research on key health behaviors and life style factors affecting disease. In its broadest sense, this RFA is responsive to a Human Capital Initiative Strategy Report entitled, "Doing the Right Thing: A Research Plan for Healthy Living," sponsored by the American Psychological Association and the National Institute of Mental Health, and prepared through a collaboration among representatives of 23 organizations. This Report noted the U.S. Public Health Service finding that seven of the 10 leading causes of death could be reduced substantially if people at risk would not only adhere to medical recommendations, but also change four other behaviors: tobacco use, exercise, diet, and alcohol abuse. The Research agenda is also responsive to recommendations emanating from the October 6-8, 1993 NIH Office of Disease Prevention and Health Promotion Conference "Disease Prevention Research at NIH: an Agenda for All" (Preventive Medicine, September 1994). The initiative is also responsive to recommendations of the September 4-6, 1991 "Report of the National Institutes of Health: Opportunities for Research on Women's Health." This report called for research on interventions for long term weight management, smoking cessation, and increasing physical activity, behaviors important for addressing osteoporosis, breast and lung cancer, heart disease, and other serious health problems affecting women. The RFA is also responsive to an 1992 Office of Alternative Medicine-sponsored workshop, "Alternative Medicine, Expanding Medical Horizons," which specifically cited the use of alternative dietary regimens for the prevention and treatment of chronic diseases. The report highlights the need for effectiveness trials in real-world settings, since even a regimen with proven efficacy can be ineffective if accompanied by a substantial drop-out rate over time.

This initiative is timely, given both the recent efforts of the Clinton Administration to curb teenage tobacco use, as well as recent priorities announced by the NCI in their 1996 Working Group Report on Priorities in Behavioral Research in Cancer Prevention and Control, which emphasized the need for studies promoting the development of innovative behavioral interventions for diet, exercise, and teenage tobacco use. Additional recent research encouragement is given in the July 1996 document entitled "Physical Activity and Health: A Report of the Surgeon General", which concluded that a daily regimen of moderate exercise will reduce risks of developing

coronary heart disease, hypertension, colon cancer, diabetes, and depression, and is important for the health of muscles, bones, and joints. Finally, the National Invitational Conference on Self Care in Later Life sponsored by the National Institute on Aging and the Partnership for Prevention concluded with a set of recommendations urging more research on theory driven interventions directed at helping older people initiate and maintain more healthy lifestyles. Attention to the clustering of different health practices was seen as particularly important for an aging population, where the emphasis is not on a particular disease, but functional limitations, disability, and increased health care use associated with disease.

The linkages between individual lifestyle behaviors and health outcomes have been well documented. The above reports and many others tell us, for example, that insufficient physical activity increases the risk of developing diabetes, depression, and colon cancer; that tobacco use affects the severity and course of asthma, both in the tobacco user and in the passive smoker; and that excess alcohol use contributes to oral and liver cancer, HIV risk, arthritis, stroke, and violence. Even more disturbing are findings which demonstrate that these behaviors have synergic adverse effects: for example, while there is a 5-fold increase in oral cancers associated with heavy alcohol use, and a 7-fold increase associated with heavy use of tobacco, combined heavy uses of alcohol and tobacco are known to cause a more than 30 fold increase in attributable risk of oral cancers. Yet while many of these linkages between lifestyles and health outcomes have become common knowledge, knowledge alone has not been found sufficient to induce desired and lasting behavior change.

Further, research has shown us that health behaviors are interrelated. For example, studies show that women have more difficulty than men in quitting smoking, and that women who succeed in quitting gain more weight than men who quit. Since smoking and excess weight have both been demonstrated to relate to outcomes such as heart disease, even a successful intervention that targets tobacco use alone may not be sufficient to improve the overall health of women. Findings such as these suggest the need for interventions that can successfully address multiple risk behaviors simultaneously.

Although a variety of theoretical models (health belief model, theory of reasoned action, prospect theory, trans-theoretical model and stages of change, theory of planned behavior, transactional model of stress and coping, social cognitive theory, social network and social support, patient - provider communication, etc.) have been developed to describe the process of health behavior change, their potential has not been fully exploited for guiding the design of behavioral interventions. This RFA acknowledges that progress could be accelerated significantly by

building on fundamental research of the behavioral sciences. Therefore, investigation of the utility of such theoretical models remains an important challenge.

It is also clear that relapse rates are very high for addictive behaviors such as tobacco use and alcohol abuse; for example most individuals who stop smoking cigarettes relapse within six months. Adherence to exercise and diet regimens is no better, despite the fact that initial success rates for various behavior change programs are very good. Thus long-term behavior change has become as challenging, if not more so, than the initiation of behavior change. Here, too, progress may be accelerated by application of appropriate theories of the behavioral sciences.

This RFA, coordinated under the auspices of the NIH Office of Behavioral and Social Sciences Research (OBSSR), is a joint effort of several Institutes and Offices of the NIH, including the NIH Office of Disease Prevention (ODP), the NIH Office of Research on Women's Health (ORWH), the NIH Office of Alternative Medicine (OAM), the NIH Office of Dietary Supplements (ODS), the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute on Aging (NIA), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Child Health and Human Development (NICHD), the National Institute of Dental Research (NIDR), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institute of Mental Health (NIMH), the National Institute of Neurological Disorders and Stroke (NINDS), and the National Institute of Nursing Research (NINR). This RFA is in line with NIH's overall mission to promote the nation's health, by increasing the scope of research on the role of human behavior and social processes in the promotion of health and prevention of disease.

The American Heart Association (AHA) is joining the NIH in this initiative, because of the RFA's responsiveness to both the AHA Expert Panel Report on Awareness versus Behavior Change, and the AHA Expert Panel Report on Compliance. AHA is sponsoring the semi-annual grantee workshops associated with this RFA.

It is hoped that the spirit of collaboration which spawned this initiative will carry forward throughout the project and beyond. Toward this end, researchers are encouraged, after a reasonable period of time for primary analyses and publication, to make the data collected as a result of this RFA readily available to future researchers wishing to use this data at their own research site. This availability may be achieved by either archiving the data and related documentation at any recognized data archive, placing the data and documentation on a publicly

available file server maintained by the grantee organization, or supplying the data and documentation at cost upon request.

Research Goals and Topics

This RFA encourages grants for the study of theory-based interventions that target initiation and maintenance of behavioral change. Applications must propose either to compare alternative theories related to mechanisms involved in behavior change (the "multiple theories" option), or to assess the utility of a particular theoretical model for changing two or more health- related behaviors (the "multiple behaviors" option). Behaviors will be restricted to those identified in the literature as among the major causes of mortality: tobacco use, excess alcohol consumption, poor diet, and inactivity. A major goal of this solicitation is to stimulate research that addresses the difficult problems of long-term behavior change, so selected theories must be directed toward both behavior change and maintenance of this change over the long-term. Partnerships between behavior change experts, intervention specialists, and appropriate health professionals are essential.

The examples listed below are not exhaustive; it is expected that additional important strategies and topics will be identified by investigators who respond to this solicitation RFA.

Studies exemplifying ways to address the "multiple theories" option:

o Examinations of how competing theories interrelate or complement each other, such as studies simultaneously varying motivation source, degree of self- efficacy, stage of change, social reinforcement, or norms;

o Examinations of the increased predictive power of multiple theories versus a single theory;

o Collaborations between investigators with different theoretical orientations to design head-to-head comparisons of the utility of different theoretical models, such as comparisons of theories with respect to their success in initiating positive behaviors (exercise, dietary change) versus extinguishing negative behaviors (smoking, drinking); or comparisons of different theories for utility in maintaining behavior change over time;

o Investigations of the relevance of different theories for changing particular behaviors in various underserved or high-risk/special need populations across the life-course, with respect to the

effectiveness of different theory based interventions for potentially vulnerable population groups (e.g., ethnic or minority populations; low income or education; the young or the very old);

o Investigations comparing different theoretical approaches for integrating multiple risk messages; for example, comparing a general intervention targeted toward multiple behavior outcomes ("healthy life style" promotion) to an intervention targeting a single behavior and assessing its effectiveness in generalizing to other risk behaviors.

Studies exemplifying ways to address the "multiple behaviors" option:

o Examinations of universal (primary) preventive interventions that target all members of the community and all behaviors of interest;

o Investigations of selective or indicated (secondary or tertiary) preventive interventions that recruit individuals on the basis of selected behaviors; multiple risk factors or behaviors of interest co-occur within the individual;

o Studies containing subcomponents that address different behaviors separately, e.g., a project with multiple substudies that investigate different aspects of a theory for their relevance to different behaviors;

o Examinations of how behaviors cluster and reinforce each other, in terms of the effects of these interrelationships on response to different interventions (e.g., comparing intervention response of people who engage in multiple behaviors to those who engage in a single risk behavior; gateway behaviors for different age groups; transfer of behavior skills from one behavior to another).

SPECIAL REQUIREMENTS

It is anticipated that a successful grant application will contain the following key elements:

Characteristics of Interventions

Interventions should be effectiveness trials in real world settings (e.g., clinic, workplace, club, church). While important, community-level interventions (e.g., studies of community-based regulatory or policy changes) will not be supported under this initiative. There must be explicit attention to specifying the nature of the proposed intervention, in terms of, for example, its

intensity, duration, and frequency of contact. Plans for assuring treatment fidelity and implementation must also be specified. Applications must explain how the design will handle external factors that can affect intervention implementation and success.
Involvement of a community advisory panel and/or partnership with a non-academic community or health organization may be helpful in devising strategies to enhance intervention design, implementation, outreach, and interpretation of findings.

Bi-Annual Meetings and Collaboration

Applicants must plan for conference calls four times a year among grantees supported as a result of the RFA, to coordinate research and share progress. In addition, application budgets must include funds to attend two collaborative meetings to be held in the Washington DC area, for three investigators from each site per year. The first collaborative meeting will occur shortly after grant award, and will focus on research designs, objectives, and possible collaborative arrangements that might foster increased productivity or efficiency in addressing the objectives proposed by the applicants. It is desirable to achieve some uniformity in measurement of key behaviors across the different funded sites. Therefore, investigators will be asked to bring their strategies for measuring exercise, smoking, diet and alcohol abuse to the first meeting, and an attempt will be made to identify a common core of key measures. After the completion of the four-year project period, NIH may invite the grant recipients to participate in a symposium to evaluate the findings and their implications for research and policy.

Plans for Long-Term Follow- Up

While initial follow-up plans may be limited by the four-year duration of this program, experimental designs must provide for at least one year follow-up in the initial grant, and propose plans for the possibility of extended follow-up with funding sought by competition through traditional investigator-initiated mechanisms, for successful or promising research projects. For example, provision should be made for maintaining contact with participants, structuring informed consent as appropriate, age of participants, or data collection. Methods must have the capacity to assess maintenance of change and confounding variables (e.g., multiple versus single risk behaviors).

Pilot Data

Preference will be given to applications with pilot data, or with experience in testing the feasibility of recruiting diverse populations, designing theory-based interventions, and assessing their outcomes. Given the call for research on multiple behaviors or intervention strategies, applicants

may not have pilot work in all aspects of their proposed work. However, they are expected to show the relevance of their previous work to the current effort. Additional pilot work on refining the intervention and assessment protocol may occur in the first year, but since recruitment accrual and intervention time-frames must permit at least one year of follow-up assessment, all sites must plan to enter the field with finalized interventions and assessments by the start of the second year.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH- supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of the Public Service Act, added by Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," which has been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), and in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Investigators may obtain copies from these sources of from the program staff or contact the person listed below. Program staff may also provide additional relevant information concerning the policy.

LETTER OF INTENT

Prospective applicants are asked to submit, by April 1, 1998, a letter of intent that includes a descriptive title of the proposed research the name, title, institution, and e-mail address of the principal investigator, and identification of any other participating institutions. Such letters are requested only for the purpose of facilitating technical assistance and review, by providing an indication of the number and scope of applications to be received; consequently, their receipt is usually not acknowledged. A letter of intent is not binding, and it will not enter into the review of any application subsequently submitted, nor is it necessary to have sent a letter of intent to submit an application.

The letter of intent is to be sent to:

Susan D. Solomon, Ph.D.
Office of Behavioral and Social Sciences Research
National Institutes of Health
7550 Wisconsin Avenue, Room 8C16, MSC 9172
Bethesda, MD 20892
FAX: (301) 480-8905
Email: ssolomon@nih.gov

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 5/95) is to be used in applying for these grants. Applications kits are available at most institutional offices of sponsored research and maybe obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, email: ASKNIH@od.nih.gov.

To identify the application as a response to this RFA, the RFA title "Innovative Approaches to Disease Prevention through Behavior Change," and number "OD-98-002," must be typed under item 2 of the face page of the application form, and the YES box must be checked.
The RFA label available in the PHS 398 application kit must be affixed to the bottom of the face page of the original copy of the application. Failure to use this label could result in delayed processing the application such that it may not reach the review committee in time for review.

Submit a signed, typewritten original of the application and four signed, exact photocopies, in one package to:

CENTER FOR SCIENTIFIC REVIEW (formerly Division of Research Grants)
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At time of submission, an additional copy of the application must also be sent under separate cover to:

Susan D. Solomon, Ph.D.
Office of Behavioral and Social Sciences Research
National Institutes of Health
7550 Wisconsin Avenue, Room 8C16, MSC 9172
Bethesda, MD 20892

All applicants must provide a Protection of Human Subjects Assurance Identification/Certification/Declaration as specified in the policy described on the Optional Form 310. If there is a question regarding the applicability of this assurance, contact the Office for Protection from Research Risks of the National Institutes of Health at (301) 496-7041.

Applications must be received by May 21, 1998. If an application is received after that date, it will be returned to the applicant. The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications previously reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by CSR, and for responsiveness by the NIH program staff. Incomplete applications will be returned to the applicant without further consideration. In addition, if program staff find that the application is not responsive to the RFA, it will be returned to the applicant without review.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by a special emphasis panel convened in accordance with NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, and assigned a priority score; those with the potential for funding will receive a second level review by the National Advisory Council of the relevant NIH institute.

Applications will be judged on the following criteria:

(1) Significance: Does the application propose either to compare alternative theories related to mechanisms involved in behavior change, or to assess the utility of a particular theoretical model for changing two or more of the following health-related behaviors: (smoking, drinking, poor diet, inactivity)? Does the research address both behavior change and maintenance of this change over the long-term? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach: Are the conceptual framework, design, methods, and analyses adequately developed, and appropriate to the aims of the project? Are the conceptual models well integrated into the design and testing of the proposed intervention? Will the intervention take place in a real world setting? Has sufficient detail about the intervention been provided to understand the intervention processes and mechanisms of change? Does the applicant acknowledge potential problem areas and consider alternative tactics? Have provisions been made for the possibility of extended follow-up, including methods capable of assessing maintenance of change and confounding variables?

(3) Innovation: Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the intervention effort go beyond previous single behavior/intervention approaches?

(4) Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)? Is there provision for partnerships between behavior change experts, intervention specialists, and appropriate health professionals?

(5) Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed experiment take advantage of unique features of the scientific and community environment, or employ useful collaborative arrangements? Is there evidence of institutional support?

Receipt and Review Schedule

Letter of Intent Receipt Date: April 1, 1998
Application Receipt Date: May 21, 1998
Initial Review: September/October 1998
Advisory Council Review: January 1999

Earliest Start Date: April 1, 1999

AWARD CRITERIA

Funding decisions will made by the sponsoring organizations, based on scientific and technical merit as determined by peer review, program priorities, content area balance, practice relevance, and the availability of funds.

INQUIRIES

Inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Program staff of the NIH are available for consultation concerning application development before or during the process of preparing an application. Potential applicants should contact program staff as early as possible for information and assistance in initiating the application process and developing an application.

General inquiries (e-mail preferred) regarding process may be directed to:

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7550 Wisconsin Avenue, Room 8C16, MSC 9172
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Substantive inquiries (e-mail preferred) regarding content, design, and application development, including whether a particular research topic falls within the scope of the RFA, may be directed to:

Patricia Bryant, Ph.D.
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AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Numbers 93.395 (NCI), 93.837 (NHLBI), 93.886 (NIA), 93.273 (NIAAA), 93.856, 93.855 (NIAID), 93.846 (NIAMS), 93.865 (NICHD), 93.848 (NIDDK), 93.121 (NIDR), 93.242 (NIMH), 93.853 (NINDS), and 93.361(NINR). Awards are made under authorization of section 301 and Title IV (42 U.S.C. 241 and 281) of the Public Health Service Act, and are administered under PHS grants policies and Federal

Regulations 42 CAR Part 52, and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive order 12372, or Health Systems Agency Review. Awards by PHS agencies will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement (April 1, 1994).

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the nonuse of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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